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<b>PTO TRANSMITTAL FORM</b> (to be used for correspondence after initial filing) PATENT & TRADEMARK OFFICE MAY 02 2005	Application Number	09/709,045
	Filing Date	November 10, 2000
	First Named Inventor	M. Rigdon Lentz
	Art Unit	1647
	Examiner Name	Lorraine Spector
	Attorney Docket Number	LEN 102
Total Number of Pages in This Submission		

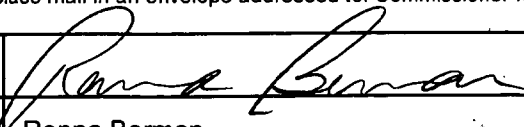
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<b>Remarks</b>		

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Firm Name	Pabst Patent Group LLP		
Signature			
Printed name	Tiffany B. Salmon		
Date	April 29, 2005	Reg. No.	55,589

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LEN 102 / 077829-00006

Receipt date: 05/04/2005

09709045 GAU: 1647

PTO/BB7 (12-04)

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Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). <b>FEE TRANSMITTAL</b> <b>For FY 2005</b> MAY 2 2005 RECEIVED & TRADEMARK OFFICE		<b>Complete if Known</b> Application Number <b>09/709,045</b> Filing Date <b>November 10, 2000</b> First Named Inventor <b>M. Rigdon Lentz</b> Examiner Name <b>L. Spector</b> Art Unit <b>1647</b> Attorney Docket No. <b>LEN 102</b>	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27			
<b>TOTAL AMOUNT OF PAYMENT</b> (\$ <b>180.00</b> )			

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For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)	
<input checked="" type="checkbox"/> Charge fee(s) indicated below <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee	
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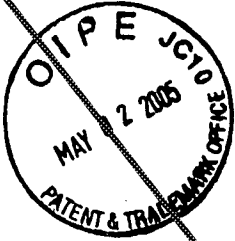
<b>FEE CALCULATION</b>							
<b>1. BASIC FILING, SEARCH, AND EXAMINATION FEES</b>							
	<b>FILING FEES</b> <b>Small Entity</b>		<b>SEARCH FEES</b> <b>Small Entity</b>		<b>EXAMINATION FEES</b> <b>Small Entity</b>		
<b>Application Type</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fees Paid (\$)</b>
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	
<b>2. EXCESS CLAIM FEES</b>							
<b>Fee Description</b>						<b>Small Entity</b> <b>Fee (\$)</b>	<b>Fee (\$)</b>
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent						50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent						200	100
Multiple dependent claims						360	180
<b>Total Claims</b> <b>14</b> - 20 or HP = <b>0</b> x <b>0.00</b> = <b>0.00</b>		<b>Extra Claims</b> <b>0</b> x <b>0.00</b> = <b>0.00</b>		<b>Fee Paid (\$)</b> <b>0.00</b>		<b>Multiple Dependent Claims</b> <b>Fee (\$)</b> <b>Fee Paid (\$)</b>	
<b>Indep. Claims</b> <b>2</b> - 3 or HP = <b>0</b> x <b>0.00</b> = <b>0.00</b>		<b>Extra Claims</b> <b>0</b> x <b>0.00</b> = <b>0.00</b>		<b>Fee Paid (\$)</b> <b>0.00</b>			
HP = highest number of total claims paid for, if greater than 20		HP = highest number of independent claims paid for, if greater than 3					
<b>3. APPLICATION SIZE FEE</b>							
If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(a).							
<b>Total Sheets</b> <b>100</b> - 100 = <b>0</b> / 50 = <b>0</b> (round up to a whole number) x <b>125</b> = <b>0.00</b>	<b>Extra Sheets</b> <b>0</b> / 50 = <b>0</b> (round up to a whole number) x <b>125</b> = <b>0.00</b>	<b>Number of each additional 50 or fraction thereof</b> <b>0</b> x <b>125</b> = <b>0.00</b>	<b>Fee (\$)</b> <b>0.00</b>	<b>Fee Paid (\$)</b> <b>0.00</b>			
<b>4. OTHER FEE(S)</b>							
Non-English Specification, \$130 fee (no small entity discount)						<b>Fees Paid (\$)</b> <b>130.00</b>	
Other: Information Disclosure Statement						<b>180.00</b>	

<b>SUBMITTED BY</b>		
Signature <b>T. Salmon</b>	Registration No. (Attorney/Agent) <b>55,589</b>	Telephone <b>(404) 879-2153</b>
Name (Print/Type) <b>Tiffany B. Salmon</b>	Date <b>April 29, 2005</b>	

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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LEN 102 / 077829-00006



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: M. Rigdon Lentz

Serial No.: 09/709,045

Art Unit: 1647

Filed: November 10, 2000

Examiner: Lorraine Spector

For: *METHOD AND SYSTEM TO REMOVE CYTOKINE INHIBITOR IN PATIENTS*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56, Applicants submit a Supplemental Information Disclosure Statement, including fifteen (15) pages of Form PTO-1449, and copies of the one hundred and ninety-four (194) documents cited therein.

This Information Disclosure Statement is being filed in accordance with 37 C.F.R. § 1.98. Applicants respectfully request consideration of this Information Disclosure Statement. The Commissioner is authorized to charge \$180.00, the fee set forth under 37 CFR § 1.17(p), to Account No. 50-3129, if necessary. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-3129.

05/03/2005 HDESTAL 00000080 503129 09709045  
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U.S.S.N.: 09/709,045

Filed: November 10, 2000

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DISCLOSURE STATEMENTReferences duplicative of those cited on  
the IDS form itself. /CMW/**U.S. Patent Applications**

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### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



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Application Number

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First Named Inventor

M. Rigdon Lentz

Group Art Unit

1647

Examiner Name

Lorraine Spector

Attorney Docket Number

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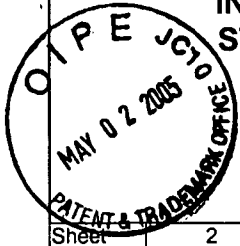
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**First Named Inventor**

M. Riadon Lentz

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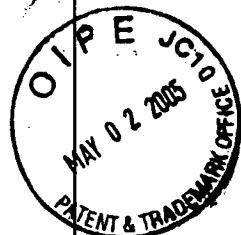
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## **Complete if Known**

Application Number		09/709,045
Filing Date		November 10, 2000
First Named Inventor		M. Rigdon Lentz
Group Art Unit		1647
Examiner Name		Lorraine Spector
Attorney Docket Number		LEN 102
Sheet	5	of 15

## **OTHER ART – NON PATENT LITERATURE DOCUMENTS**

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		ABBRUZZESE, et al., "A phase II trial of recombinant human interferon-gamma and recombinant tumor necrosis factor in patients with advanced gastrointestinal malignancies: Results of a trial terminated by excessive toxicity" <i>Journal of Biological Response Modifiers</i> 9:522-527 (1990).					
		ADOLF AND APFLER, "A monoclonal antibody-based enzyme immunoassay for quantitation of human tumor necrosis factor binding protein I, a soluble fragment of the 60kDa TNF receptor, in biological fluids" <i>J. Immunol. Meth.</i> 143:127-136 (1991).					
		AJANI, et al., "Phase I and II studies of the combination of recombinant human interferon-γ and 5-fluorouracil in patients with advanced colorectal carcinoma" <i>Journal of Biological Response Modifiers</i> 8:140-146 (1989).					
		ALBERTINI, et al., "Limiting dilution analysis of lymphokine-activated killer cell precursor frequencies in peripheral blood lymphocytes of cancer patients receiving interleukin-2 therapy" <i>Journal of Biological Response Modifiers</i> 9:456-462 (1990).					
		AREND, "Inhibiting the effects of cytokines in human diseases" <i>Adv. Int. Med.</i> 40:365-394 (1995).					
		AVNER, et al., "Therapeutic murine monoclonal antibodies developed for individual cancer patients" <i>Journal of Biological Response Modifiers</i> 8:25-36 (1989).					
		BALCEWICZ-SABLINSKA, et al., "Pathogenic <i>Mycobacterium tuberculosis</i> evades apoptosis of host macrophages by release of TNF-R2, resulting in inactivation of TNF-α" <i>J. Immunol.</i> 161:2636-2641 (1998).					
		BALIKO, et al., "Th2 biased immune response in cases with active <i>Mycobacterium tuberculosis</i> infection and tuberculin anergy" <i>FEMS Immunol. Med. Micro.</i> 22:188-204 (1998).					
		BERMUDEZ AND CHAMPSI, "Infection with <i>Mycobacterium avium</i> induces production of interleukin-10 (IL-10), and administration of anti-IL-10 antibody is associated with enhanced resistance to infection in mice" <i>Infect. Immun.</i> 61:3093-3097 (1993).					
		BEUTLER AND CERAMI, "The biology of cachectin/TNF-A primary mediator of the host response" <i>Ann. Rev. Immunol.</i> 7:625-655 (1989).					
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Application Number	09/709,045
Filing Date	November 10, 2000
First Named Inventor	M. Rigdon Lentz
Group Art Unit	1647
Examiner Name	Lorraine Spector
Attorney Docket Number	LEN 102

Sheet 6 of 15

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		BLAUER, et al., "Modulation of the antilisterial activity of human blood-derived macrophages by activating and deactivating cytokines" <i>J. Interferon Cytokine Res.</i> 15:105-114 (1995).	
		BOMAN, et al., "Phase I study of recombinant gamma-interferon (rIFN- $\gamma$ )" <i>Journal of Biological Response Modifiers</i> 7:438-446 (1988).	
		BRUNTSCH, et al., "phase II study of recombinant human interferon- $\gamma$ in metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:335-338 (1990).	
		BUKOWSKI, et al., "Phase I trial of continuous infusion of recombinant interleukin-2 and intermittent recombinant interferon- $\alpha_{2a}$ . Clinical effects" <i>Journal of Biological Response Modifiers</i> 9:538-545 (1990).	
		CAULFIELD, et al., "Phase I1-Ib trial of an anti-G <sub>D3</sub> monoclonal antibody in combination with interferon- $\alpha$ in patients with malignant melanoma" <i>Journal of Biological Response Modifiers</i> 9:319-328 (1990).	
		CHAMBRIER, et al., "Hormonal and metabolic effects of chronic interleukin-2 infusion in cancer patients" <i>Journal of Biological Response Modifiers</i> 9:251-255 (1990).	
		CHOUAIB, et al., "More insights into the complex physiology of TNF" <i>Immunol. Today</i> 12(5):141-145 (1991).	
		COCLET-NININ, et al., "Interferon-beta not only inhibits interleukin-1 $\beta$ and tumor necrosis factor- $\alpha$ but stimulates interleukin-1 receptor antagonist production in human peripheral blood mononuclear cells" <i>Eur. Cytokine Network</i> 8(4):345-349 (1997).	
		COLMAN, et al., <u>Hemostasis and Thrombosis: Basic Principles and Clinical Practice</u> 2nd. Edition (Colman, et al., eds.) pp. 63-67 J.B. Lippincott: Philadelphia, PA, 1987.	
		COX, et al., "Phase II study of human lymphoblastoid interferon in patients with multiple myeloma" <i>Journal of Biological Response Modifiers</i> 7:318-325 (1988).	
		CREAVEN, et al., "Initial clinical trial of the macrophage activator muramyl tripeptide-phosphatidylethanolamine encapsulated in liposomes in patients with advanced cancer" <i>Journal of Biological Response Modifiers</i> 9:492-498 (1990).	

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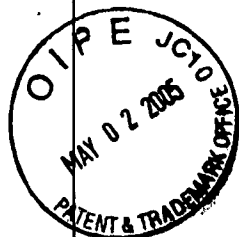
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Attorney Docket Number		LEN 102

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		CROGHAN, et al., "A phase I trial of recombinant interferon- $\alpha$ and $\alpha$ -difluoromethylornithine in metastatic melanoma" <i>Journal of Biological Response Modifiers</i> 7:409-415 (1988).	
		D'ANDREA, et al., "Interleukin 10 (IL-10) inhibits human lymphocyte interferon $\gamma$ production by suppressing natural killer cell stimulatory factor/IL-12 synthesis in accessory cells" <i>J. Exp. Med.</i> 178:1041-1048 (1993).	
		DIMERY, et al., "Recombinant interferon- $\gamma$ in the treatment of recurrent nasopharyngeal carcinoma" <i>Journal of Biological Response Modifiers</i> 8:221-226 (1989).	
		DINARELLO, "Induction of interleukin-I and interleukin-I receptor antagonist" <i>Sem. In Oncol.</i> 24(no. 3, Suppl. 9):81-93 (1997).	
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		ENGELHARDT, et al, "Biological response to intravenously administered endotoxin in patients with advanced cancer" <i>Journal of Biological Response Modifiers</i> 9:480-491 (1990)	
		ENGELMANN, et al., "Two tumor necrosis factor-binding proteins purified from human urine" <i>J. Biol. Chem.</i> 265(3):1531-1536 (1990).	
		ERIKS AND EMERSON, "Temporal effect of tumor necrosis factor alpha on murine macrophages infected with <i>Mycobacterium avium</i> " <i>Infect. Immun.</i> 65(6):2100-2106 (1997).	
		ETGES AND MULLER, "Progressive disease or protective immunity to <i>Leishmania</i> major infection: the result of a network of stimulatory and inhibitory interactions" <i>J. Mol. Med.</i> 76:372-390 (1998).	
		FAREED, et al., "Novel antigenic markers of human tumor regression" <i>Journal of Biological Response Modifiers</i> 7:11-23 (1988).	
		FAVROT, et al., "Functional and immunophenotypic modifications induced by interleukin-2 did not predict response to therapy in patients with renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:167-177 (1990).	

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		FERNANDES AND BALDWIN, "Interleukin-10 downregulates protective immunity to <i>Brucella abortus</i> " <i>Infect. Immun.</i> 63:1130-1133 (1995).	
		FOON, et al., "A prospective randomized trial of $\alpha_2\beta_2$ -interferon/ $\gamma$ -interferon or the combination in advanced metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 7:540-545 (1988).	
		FROST, et al., "Interleukin-6 induction by a muramyltripeptide derivative in cancer patients" <i>Journal of Biological Response Modifiers</i> 9:160-166 (1990).	
		GADDUCCI, et al., "Serum levels of soluble receptors for tumor necrosis factor (p55 and p75 sTNFr) in endometrial cancer" <i>Anticancer Res.</i> 16:3125-3128 (1996).	
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		GREENBLATT, et al., "The type B receptor for tumor necrosis factor-alpha" <i>Blood</i> 80:1339-1346 (1992).	
		GUSTAVSON, et al., "Pharmacokinetics of teceleukin (Recombinant human inteleukin-2) after intravenous or subcutaneous administration to patients with cancer" <i>Journal of Biological Response Modifiers</i> 8:440-449 (1989).	
		HANDZEL, et al., "Immunomodulation of T cell deficiency in humans by thymic humoral factor: from crude extract to synthetic thymic humoral factor- $\gamma_2$ " <i>Journal of Biological Response Modifiers</i> 9:269-278 (1990).	
		HANK, et al., "Depressed <i>in vitro</i> T cell responses concomitant with augmented interleukin-2 responses by lymphocytes from cancer patients following <i>in vivo</i> treatment with interleukin-2" <i>Journal of Biological Response Modifiers</i> 9:5-14 (1990).	
		HERCEND, et al., "Immunotherapy with lymphokine-activated natural killer cells and recombinant interleukin-2: A feasibility trial in metastatic renal cell carcinoma" <i>Journal of Biological Response Modifiers</i> 9:546-555 (1990).	

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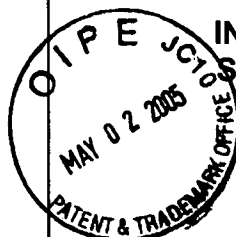

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Sheet 9 of 15

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		HERTLER, et al., "A phase I study of T101-ricin A chain immunotoxin in refractory chronic lymphocytic leukemia" <i>Journal of Biological Response Modifiers</i> 7:97-113 (1988).	
		HIMMLER, et al., "Molecular cloning and expression of human and rat tumor necrosis factor receptor chain (p60) and its soluble derivative, tumor necrosis factor-binding protein" <i>DNA and Cell Biol.</i> 9(10):705-715 (1990).	
		JACOBS, et al., "minimal antigenicity of intron A in human recipients demonstrated by three analytical methods" <i>Journal of Biological Response Modifiers</i> 7:447-456 (1988).	
		JAKOBSEN, et al., "Decreased antitoxic activities among children with clinical episodes of malaria" <i>Infect. Immun.</i> 66(4):1654-1659 (1998).	
		JAKSCHIES, et al., "Emergence and decay of the human Ms homolog in cancer patients during and after interferon- $\alpha$ therapy" <i>Journal of Biological Response Modifiers</i> 9:305-312 (1990).	
		KALMANTI, et al., "Serum levels of tumor necrosis factor soluble interleukin 2 receptor as markers of disease activity and prognosis in childhood leukemia and lymphoma" <i>Int. J. Hematol.</i> 57:147-152 (1993).	
		KAUFMANN, et al., "T cells and cytokines in intracellular bacterial infections: experiences with <i>Mycobacterium bovis</i> BCG" <i>Ciba Fdn. Symp.</i> 195:123-132 (1995).	
		KELLOKUMPU-LEHTINEN, et al., "Recombinant interferon- $\alpha$ 2a and vinblastine in advanced renal cell cancer: A clinical phase I-II study" <i>Journal of Biological Response Modifiers</i> 9:439-444 (1990).	
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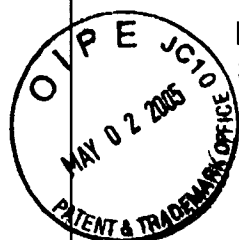
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Sheet 10

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		KRIGEL, et al., "Treatment of epidemic kaposi's sarcoma with a combination of interferon-alpha 2b and etoposide" <i>Journal of Biological Response Modifiers</i> 7:359-364 (1988).	
		LANTZ, et al., "Infusion of tumor necrosis factor (TNF) causes an increase in circulating TNF-binding protein in humans" <i>Cytokine</i> 2(6):402-406 (1990).	
		LASZLO, et al., "Phase I studies of recombinant interferon- $\gamma$ " <i>Journal of Biological Response Modifiers</i> 9:185-193 (1990).	
		LAUCELLA, et al., "Papel de las citoquinas en la resistencia y patologia durante la infeccion con <i>Trypanosoma cruzi</i> " <i>Revista Argentina de Microbiologia</i> , 28:99-109 (1996).	
		LENTZ, et al., "Apheresis of low molecular weight protein fraction and the onset of labor" <i>Journal of Clinical Apheresis</i> 5:62-67 (1990).	
		LENTZ, "The phylogeny of oncology" <i>Mol. Biother.</i> 2:137-144 (1990).	
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Application Number		09/709,045	
Filing Date		November 10, 2000	
First Named Inventor		M. Rigdon Lentz	
Group Art Unit		1647	
Examiner Name		Lorraine Spector	
Attorney Docket Number		LEN 102	
Sheet	11	of	15

**OTHER ART -- NON PATENT LITERATURE DOCUMENTS**

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		MACA, "Inhibition of the growth of lewis lung carcinoma by indomethacin in conventional, nude, and beige mice" <i>Journal of Biological Response Modifiers</i> 9:568-580 (1990).	
		MARSHALL, et al., "Effects of coumarin (12-benzopyrone) and cimetidine on peripheral blood lymphocytes, natural killer cells, and monocytes in patients with advanced malignancies" <i>Journal of Biological Response Modifiers</i> 8:62-69 (1989).	
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Group Art Unit	1647
Examiner Name	Lorraine Spector
Attorney Docket Number	LEN 102

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		PAOLOZZI, et al., "Phase I trial of recombinant interleukin-2 and recombinant $\beta$ -interferon in refractory neoplastic diseases" <i>Journal of Biological Response Modifiers</i> 8:122-139 (1989).	
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November 10, 2000

First Named Inventor

M. Rigdon Lentz

Group Art Unit

1647

Examiner Name

Lorraine Spector

Attorney Docket Number

LEN 102

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		SATO, et al., "induction of bone formation in an adenoid cystic carcinoma of the maxillary sinus by adoptive immunotherapy involving intra-arterial injection of lympholine-activated killer cells and recombinant interleukin-2 in combination with radiotherapy" <i>Journal of Biological Response Modifiers</i> 9:329-334 (1990).	
		SCHAADT, et al., "Phase II study of recombinant human tumor necrosis factor in colorectal carcinoma" <i>Journal of Biological Response Modifiers</i> 9:247-250 (1990).	
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Group Art Unit	1647
Examiner Name	Lorraine Spector
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		WHITEHEAD, et al., "A phase II trial of recombinant tumor necrosis factor in patients with metastatic colorectal adenocarcinoma: A southwest oncology group study" <i>Journal of Biological Response Modifiers</i> 9:588-591 (1990).	
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